REMARKS

Status of the Claims

Claims 1-27 remain pending. Claims 7, 8, 10, 11, 12, 14, 16, 17, 19, 23, 24 and 26 are amended to correct minor inadvertencies therein. No narrowing in claim scope is intended or effected.

Objection to the Drawings

Certain drawings are objected to as not containing a legend such as "Prior Art" because only that which is old is allegedly illustrated therein. Applications respectfully traverse this objection.

Specifically, the present invention is directed to intraluminal stents, which comprise (a) a metallic reinforcing component and (b) a biodegradable polymeric material covering at least a portion of the metallic reinforcing component. In the stents of the present invention, the metallic reinforcing component provides structural reinforcement for the stent. However, the metallic reinforcing component is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

Figs. 1-4, 7 and 8 depict metallic reinforcing structures in accordance with the present invention, which are suitable for use in such stents.

Similarly, Figs. 5a, 5b, 6, 9a and 9b are views of metallic reinforcing structures in accordance with the present invention which are suitable for use in such stents. In addition, these drawings further illustrate the use of biodegradable polymeric materials in conjunction with the metallic reinforcing structures, in accordance with the present invention.

Although the specific geometric design of the metallic reinforcing structures illustrated in the drawings may have an outward appearance like those found in prior art stents, the metallic reinforcing structures of the present invention differ from prior art metallic structures in that they have insufficient mechanical integrity, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency

of a lumen upon implantation of the stent into the lumen. Therefore, something other than "that which is old" is depicted in the drawings.

For at least this reason, reconsideration and withdrawal of the objection to the drawings are requested.

Claim rejections under 35 U.S.C. §112, second paragraph

Claims 7, 11, 12, 14, 16, 17, 19, 23, 24 and 26 are rejected under 35 U.S.C. §112, second paragraph. These rejections are believed to be moot in view of the claim amendments presented above.

Reconsideration and withdrawal of the rejection of claims 7, 11, 12, 14, 16, 17, 19, 23, 24 and 26 under 35 U.S.C. §112, second paragraph are therefore requested.

Rejection of claims 1-10, 13, 15, 18, 20-22, 25 and 27 under 35 U.S.C. §102(e)

Claims 1-10, 13, 15, 18, 20-22, 25 and 27 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,824,049 (Ragheb). This rejection and its supporting remarks are respectfully traversed.

Claim 1 is directed to an intraluminal stent, which comprises (a) a metallic reinforcing component and (b) a biodegradable polymeric material covering at least a portion of the metallic reinforcing component. The metallic reinforcing component in the stent provides structural reinforcement for the stent. However, the metallic reinforcing component is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

As noted in paragraph [0031] of the present specification, the composite intraluminal stent of the claimed invention, in contrast with known composite stents, utilizes both the metallic component and the biodegradable polymeric component to provide the mechanical properties necessary for maintaining the patency of the lumen upon implantation of the stent into a body lumen. Whereas known composite stents typically employ a biodegradable polymeric component as a coating, for example, for incorporating and providing localized release therefrom of a therapeutic agent, such a coating layer does not provide the stent with mechanical strength necessary for

maintaining luminal patency upon implantation. This task is left to the metallic component.

As noted in paragraph [0034] of the present specification, the composite intraluminal stent of the present invention provides distinct advantages relative to composite stents in which the biodegradable polymeric component does not substantially contribute to the mechanical strength of the stent. For example, because the metallic reinforcing component is not relied on as the sole source of mechanical strength, a stent can be provided that advantageously utilizes less metal and more biodegradable polymeric material. Metallic materials are often more rigid and less biocompatible than biodegradable polymeric materials. For instance, the relative rigidity of metallic materials can compromise the goal of providing a stent that is biomechanically compatible, i.e., compliant with the contacting lumen walls. Because less metal is utilized in a stent in accordance with the present invention, the metallic component of the stent can be constructed from thinner and more flexible metallic filaments or sheets to provide a flexible metallic reinforcing component. Upon in vivo biodegradation of the polymeric material, the remaining flexible metallic framework of the stent will be advantageously less bulky and have a smaller surface area in direct contact with the lumen walls. At such point, the remaining flexible metallic framework of the stent will be more compliant with the contacting lumen walls and be less likely to cause damage or injury to the same if left implanted indefinitely.

By appropriate selection of metallic and biodegradable polymeric materials, the present invention provides an enhanced ability to customize the mechanical properties of an intraluminal stent dependent, for example, on the time-dependent changes associated with lumen healing or remodeling. The present invention thus relies on the desirable properties of both metallic and biodegradable polymeric materials to provide a composite biomechanically compatible stent. See paragraph [0036].

Ragheb neither teaches nor suggests a stent, such as that claimed in claim 1, which contains a metallic reinforcing component that provides structural reinforcement for the stent, but which is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation

of the stent into the lumen. Accordingly, claim 1, and claims 2-10, 13, 15, 18, 20-22, 25 and 27 depending therefrom, are patentable over Ragheb.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1-10, 13, 15, 18, 20-22, 25 and 27 under 35 U.S.C. §102(b) as anticipated by Ragheb are respectfully requested.

Rejection of claims 1, 5-10, 12, 13 and 14 under 35 U.S.C. §102(e)

Claims 1, 5-10, 12, 13 and 14 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,725,567 (Wolff). This rejection and its supporting remarks are respectfully traversed.

As noted above, claim 1 is directed to an intraluminal stent, which comprises (a) a metallic reinforcing component and (b) a biodegradable polymeric material covering at least a portion of the metallic reinforcing component. The metallic reinforcing component in this stent provides structural reinforcement for the stent. However, the metallic reinforcing component is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

This is advantageous, for instance, in that a stent is provided which utilizes both the metallic component and the biodegradable polymeric component to initially provide the mechanical properties necessary for maintaining the patency of the lumen upon implantation of the stent into a body lumen. Because less metal is utilized in a stent in accordance with the present invention, the metallic component of the stent can be constructed from thinner and more flexible metallic filaments or sheets to provide a flexible metallic reinforcing component. Upon in vivo biodegradation of the polymeric material, the remaining flexible metallic framework of the stent will be advantageously less bulky and have a smaller surface area in direct contact with the lumen walls. At such point, the remaining flexible metallic framework of the stent will be more compliant with the contacting lumen walls and less likely to cause damage or injury thereto if left implanted indefinitely. Moreover, by appropriate selection of metallic and biodegradable polymeric materials, the present invention provides an enhanced ability to customize the

mechanical properties of an intraluminal stent dependent, for example, on the time-dependent changes associated with lumen healing or remodeling.

Wolff neither teaches nor suggests a stent, such as that claimed in claim 1, which contains a metallic reinforcing component that provides structural reinforcement for the stent, but which is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

The Office Action states that "Figure 14 shows that the polymeric material (18) provides support for the filaments (12), in that 'the bonding at the juncture prevents the individual filaments from sliding relative to each other, which improves radial strength' (column 7, lines 20-22)." However, the ensuing description at column 7, lines 26-27 makes clear that the "bonding at the juncture" involves melting the filament junctures at elevated temperatures, rather than bonding them with a polymeric material as implied in the Office Action. Moreover, even assuming for the sake or argument that Wolff did contain such a teaching, Wolff would still not teach or suggest a stent which contains a metallic reinforcing component that provides structural reinforcement for the stent, but which is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

Accordingly, claim 1, and claims 5-10, 12, 13, and 14 depending therefrom, are patentable over Wolff.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1, 5-10, 12, 13, and 14 under 35 U.S.C. §102(b) as anticipated by Ragheb are respectfully requested.

Rejection of claims 2 and 11 under 35 U.S.C. §103(a)

Claims 2 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wolff in view of U.S. Patent No. 5,630,840 (Mayer). Applicant respectfully traverses this rejection and its supporting remarks.

For example, as noted above, independent claim 1 is neither anticipated by nor obvious in view of Wolff. Mayer is cited for its alleged teachings vis-à-vis filaments requiring more that one metal and the use of various alloys as stent materials, which

teachings do not make up for the above-noted deficiencies in Wolff. For at least these reasons, it is respectfully submitted that independent claim 1 is patentable over Wolff and Mayer.

Claims 2 and 11, which depend from claim 1, are therefore patentable over Wolff and Mayer for at least the same reasons as is claim 1. Accordingly, reconsideration and withdrawal of the rejection of claims 2 and 11 under 35 U.S.C. §103(a) as being unpatentable over Wolff in view of Mayer are respectfully requested.

Rejection of claims 14, 16, 17, 19, 23, 24 and 26 under 35 U.S.C. §103(a)

Claims 14, 16, 17, 19, 23, 24 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb in view of Wolff. Applicant respectfully traverses this rejection and its supporting remarks.

For example, independent claim 1 is neither anticipated by nor obvious in view of Ragheb and Wolff, at least because neither of these references teaches or suggests a stent containing a metallic reinforcing component that provides structural reinforcement for the stent, but which is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

Claims 14, 16, 17, 19, 23, 24 and 26, which depend from claim 1, are therefore patentable over Ragheb and Wolff for at least the same reasons as is claim 1. Accordingly, reconsideration and withdrawal of the rejection of claims 14, 16, 17, 19, 23, 24 and 26 under 35 U.S.C. §103(a) as being unpatentable over Ragheb in view of Wolff are respectfully requested.

CONCLUSION

Applicants submit all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

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The Office is authorized to charge the additional claims fee as well as any other fees required to deposit account number 50-1047.

Respectfully submitted,

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